

REMARKS

Please reconsider the application in view of the above amendments and the following remarks. Applicant thanks the Examiner for carefully considering this application.

More specifically, this Amendment and Response is being filed in response to a Final Office Action, dated September 16, 2010, and an Advisory Action, dated January 3, 2011.

This Amendment and Response is being filed with a Request for Continued Examination ("RCE") and a Petition for a Two Month Extension of Time, with all necessary Large Entity Fees paid. Accordingly, this Amendment and Response is timely by being filed on or before February 16, 2011. Applicants respectfully request that the finality of the rejection of September 16, 2010, be removed in light of the accompanying RCE and that the Examiner consider the instant Amendments and Remarks.

On December 16, 2010, Applicants filed a Rule 116 Reply to the Final Office Action, including amendments to claims 1, 6, 13, 19, and 20-24, and canceled claim 16. In the Advisory Action, the Examiner indicated that these amendments were entered. Accordingly, this Amendment and Response treats the claims as amended on December 16, 2010.

Applicant respectfully asserts that for the reasons discussed below, the claims, as amended herein, are in condition for allowance. Therefore, the Examiner is requested to please consider the amended claims and the arguments below and to issue a

Notice of Allowance.

Disposition of Claims

Claims 1 – 15 and 17 – 32 are pending and under consideration. Claim 16 was previously canceled without prejudice or acquiescence.

Claim 1 is independent. The remaining claims depend, directly or indirectly, from claim 1.

Claim Amendments

Claims 1 and 27 has been amended. The amendment to claim 1, which affects every pending claim since all depend directly or indirectly from claim 1, is discussed below.

Claim 27 was amended to correct the spelling of the word “fiber.”

No new matter has been introduced by these amendments.

Claim Rejections under 35 U.S.C. § 103

Claims 1-10, 12-14, 16-19, 25, 26, and 29-32

Claims 1-10, 12-14, 16-19, 25, 26, and 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brocchini et al. (U.S. 2002/0082362) (hereinafter “Brocchini”) in further view of Neuenschwander et al. (U.S. 5,665,831) (hereinafter “Neuenschwander”). Claim 1 has been amended. To the extent that this rejection may still apply to the amended claims, this rejection is respectfully traversed.

First, the main position of the Examiner in rejecting claim 1 and all other claims is that Brocchini discloses a biodegradable polyacetal polymer having the properties of the polymer of the claimed invention except for lacking a specific diol comprising a polyester. However, the Examiner asserts that Brocchini teaches that “the diol may comprise any diol suitable for use in biomaterials.”

The Examiner then asserts that Neuenschwander “teaches biocompatible block copolymers comprising macrodiols” including polyesters.

Finally, the Examiner asserts that one of ordinary skill in the art at the time of the invention would have found it *obvious to combine the teaching of Brocchini with Neuenschwander to substitute* the diols / polyester of Neuenschwander *into Brocchini*, resulting in the diols and polymers of the claimed invention.

The Examiner is basing the “obviousness” of the substitution of the diols of Neuenschwander with those of Brocchini on US patent law that holds that it is *obvious to substitute “equivalents known for the same purpose.”* Under this law, “it is obvious to combine two compositions *each of which is taught by the art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.*”

Of course, the key to showing that this type of obviousness rejection is not properly based on US law is to show that the deficiency in the primary art that an Examiner seeks to fill by obtaining a substitute from another prior art reference is not an equivalent known for the same purpose and thus “it is [*not*] obvious to combine two

compositions each of which is taught by the art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.”

More specifically, the Examiner admits that the primary reference, Brocchini, does not teach a specific diol comprising polyester. But, the Examiner argues that the claimed invention would have been obvious because it would have been obvious to *substitute* the “biocompatible block copolymers comprising macrodiols including polyesters” of the secondary reference, Neuenschwander, into Brocchini to obtain the claimed invention.

This argument must fail because the art is clear that if one were to substitute the polyesters of Neuenschwander into Brocchini one would *not* be substituting “equivalents known for the same purpose,” and that it would therefore *not* be obvious “to combine [the] two compositions [because the art does *not* teach that] each of which substituted composition is taught by the art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.”

Specifically, amended claim 1 requires the claimed polymer to be a “biodegradable segmented block copolymer that is *insoluble* under physiological conditions.” Brocchini clearly teaches that its polymers are and must be soluble under physiological conditions. Indeed, the solubility of the polymers of Brocchini is an essential aspect of its polymers because they are used in soluble form for the delivery of drugs in vivo. Hence, the polymers of Brocchini must be soluble in physiological conditions.

On the other hand, Neuenschwander clearly teaches that its polymers must be insoluble under physiological conditions because its polymers are used as solid

components of medical implants. Therefore, the polymers of Neuenschwander must be solid in physiological conditions in order to act as solid medical implants.

Thus, it is clear from the references the Examiner seeks to combine that one would not find it obvious to substitute a component from Neuenschwander to use in Brocchini because the references explicitly teach that one would not “combine the two compositions such that each of the *substituted compositions is taught by the art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.*”

In fact, the exact opposite is explicitly taught by Brocchini and Neuenschwander. Based on the opposing teaching of the references, one skilled in the art would not find it obvious to substitute a component from an insoluble polymer patent (Neuenschwander) into a patent teaching a soluble polymer (Brocchini) and even if they did, it is certainly not true that, as required by US law, a substituted composition taught by one reference (Brocchini or Neuenschwander) would be taught by this art “to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.”

Again, the purpose of the Brocchini reference is to produce soluble polymers for drug delivery in vivo, while the purpose of the Neuenschwander patent is to produce insoluble polymers for use in solid medical implants in vivo.

Therefore, the Examiner has failed to justify the assertion that it would have been obvious for one skilled in the art to select “interchangeable” components from the Neuenschwander patent which is clearly for solid insoluble polymers in physiological

conditions to substitute into Brocchini, which is clearly for soluble polymers in physiological conditions.

In fact, the Neuenschwander and Brocchini references would teach one skilled in the art away from making any combinations or interchanges between the polymer components of each. A skilled artisan trying to create an insoluble polymer as is claimed would not seek components as interchangeable from a patent that teaches only soluble polymers as does Brocchini. It is well established US law that where the prior art teaches away from combining references the combination would not have been obvious.

Therefore, for the above reasons, applicant respectfully submits that the amended claims are not obvious over any combination of Neuenschwander and Brocchini.

Claim 11

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brocchini in view of Neuenschwander as applied to claim 1 above, in further view of Shalaby (U.S. 6,503,991) (hereinafter "Shalaby"). Claim 1 has been amended. To the extent that this rejection may still apply to the amended claims, this rejection is respectfully traversed.

As noted above, claim 1 is patentable over Brocchini in view of Neuenschwander.

Shalaby does not remedy the lack of obviousness of combining Brocchini with Neuenschwander to create the subject matter of claim 1. Because claim 11 depends from claim 1, it too is, therefore, not obvious.

Claims 15, 25, and 27

Claims 15, 25, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brocchini in view of Neuenschwander as applied to claims 1 and 14 above, in further view of Wise et al. (U.S. 6,071,982) (hereinafter “Wise”). Claim 1 has been amended. To the extent that this rejection may still apply to the amended claims, this rejection is respectfully traversed.

As noted above, claim 1 is patentable over Brocchini in view of Neuenschwander.

Wise does not remedy the lack of obviousness of combining Brocchini with Neuenschwander to create the subject matter of claim 1. Because claims 15, 25, and 27 depend from claim 1, they too are, therefore, not obvious.

Claims 20 and 22

Claims 20 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brocchini in view of Neuenschwander as applied to claim 19 above, in further view of Pathak et al. (U.S. 6,923,986) (hereinafter “Pathak”). Claim 1 has been amended. To the extent that this rejection may still apply to the amended claims, this rejection is respectfully traversed.

As noted above, claim 1 is patentable over Brocchini in view of Neuenschwander.

Pathak does not remedy the lack of obviousness of combining Brocchini with Neuenschwander to create the subject matter of claim 1. Because claims 20 and 22 depend from claim 1, they too are, therefore, not obvious.

Claim 21

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brocchini in view of Neuenschwander as applied to claim 19 above, in further view of Tormala (U.S. 6,579,533) (hereinafter "Tormala"). Claim 1 has been amended. To the extent that this rejection may still apply to the amended claims, this rejection is respectfully traversed.

As noted above, claim 1 is patentable over Brocchini in view of Neuenschwander.

Tormala does not remedy the lack of obviousness of combining Brocchini with Neuenschwander to create the subject matter of claim 1. Because claim 21 depends from claim 1, it too is, therefore, not obvious.

Claim 23

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brocchini in view of Neuenschwander as applied to claim 19 above, in further view of Uhrich (U.S. 2002/0071822) (hereinafter "Uhrich"). Claim 1 has been amended. To the extent that this rejection may still apply to the amended claims, this rejection is respectfully traversed.

As noted above, claim 1 is patentable over Brocchini in view of Neuenschwander.

Uhrich does not remedy the lack of obviousness of combining Brocchini with Neuenschwander to create the subject matter of claim 1. Because claim 23 depends from claim 1, it too is, therefore, not obvious.

Claim 24

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brocchini in view of Neuenschwander as applied to claim 19 above, in further view of Heller (U.S. 7,045,589) (hereinafter "Heller"). Claim 1 has been amended. To the extent that this rejection may still apply to the amended claims, this rejection is respectfully traversed.

As noted above, claim 1 is patentable over Brocchini in view of Neuenschwander.

Heller does not remedy the lack of obviousness of combining Brocchini with Neuenschwander to create the subject matter of claim 1. Because claim 24 depends from claim 1, it too is, therefore, not obvious.

Conclusion

Applicant believes the application is in condition for allowance. If this belief is incorrect, or other issues arise, the Examiner is encouraged to contact the undersigned at the telephone number listed below. Please apply any charges not covered, or any credits, to Deposit Account 50-0591 (Reference Number 17771/004001).

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Respectfully submitted,

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